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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,203	09/23/2003	Michael P. Wallace	2024730-7034622001 (03-24	2638

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Bingham McCuthen, LLP
Three Embarcadero, Suite 1800
San Francisco, CA 94111-4067

EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,203	WALLACE, MICHAEL P.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *4,5,9,14-17,22,23 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,10-13,18-21,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/9/05,12/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS 9/23/03*.

DETAILED ACTION

Election/Restrictions

Applicant's election of specie #2 in the reply filed on 11/07/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4, 5, 9, 14-17, 22, 23 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/07/2005.

Claims 1-3, 6-8, 10-13, 18-21, 24 and 25 will be examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelson (USPN 5,749,894).

Regarding claims 1 and 8, Engelson discloses a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a first material (102) that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted at a treatment site in the patient's body, see col. 1-9, particularly col. 6 and figures 1-4 and 10A-12C.

Regarding claim 2, Engelson further discloses a second material (104) having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the device when heated directly or indirectly by the external energy source, see col.4, lines 26-46, col. 6, lines 11-29 and col.8, line 11 through col. 9, line 37 and figures 1, 2 and 10A-12C.

Regarding claim 3, Engelson further discloses the second material is embedded in one or more portions (outer layer of the device, 104) of the device, such that, when heated directly or indirectly by the external energy source and allowed to cool in the body, the one or more portions are at least partially fused together to stabilize the vaso-occlusive device in a deployed configuration, see col. 6, lines 11-29 and col.8, line 11 through col. 9, line 37 and figures 1, 2 and 10A-12C.

Claims 1-3, 7, 10-13, 18-21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ken et al. (USPN 5,853,418).

Regarding claims 1, 7, 10, 11, 18-21 and 25, Ken et al. disclose a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a helically wound coil (coiled formed by 102 and its analogous counterparts in the other embodiments) forming a lumen and formed of platinum (see col. 4, lines 47-60), a filament/heating member (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a first highly resistive, ferrous material (contains iron), the first material that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted at a treatment site in the patient's body, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D.

Regarding claims 2, 3, 12 and 13, Ken et al. further disclose a second material (polyethylene) having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the heating member when heated directly or indirectly by the external energy source and wherein the second material is embedded in one or more portions of the coil, such that, when heated by the heating member and allowed to cool in the body, the one or more portions are at least partially fused together to stabilize the coil in a deployed configuration, see col. 5, line 64 through col. 6, line 62 and figures 1A-2C.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Bose et al. (USPN 6,605,111 B2).

Regarding claims 6 and 24, Ken et al. disclose the claimed invention except for a bioactive agent that is activated when the device is heated. Bose et al. disclose endovascular thin film devices and methods for treating and preventing stroke and teach

> *"Where appropriate, bioactive agents can be incorporated in the devices. In this case, the precursor material that makes up the device is mixed with a bioactive ingredient and a biodegradable monomer which is also polymerized in situ to form the repair device. As the biodegradable polymer degrades, it releases the bioactive ingredient at the site of the device.*
>
> *Preferred polymers to mix with the precursors to form an endovascular thin film device which releases active ingredients are polyesters in the polylactide/polyglycolide family. These polymers have received a great deal of attention in the drug delivery and tissue regeneration areas for a number of reasons. They have been in use for over twenty years in surgical sutures, are Food and Drug Administration approved, and have a long and favorable clinical record. A wide range of physical properties and degradation times can be achieved by varying the monomer ratios in lactide/glycolide copolymers: poly-L-lactic acid (PLLA) and poly-glycolic acid (PGA) exhibit a high degree of crystallinity and degrade relatively slowly, while copolymers of PLLA and PGA, PLGAs are amorphous and are rapidly degraded. There are essentially no limitations on the bioactive agents that can be incorporated in the repair devices, although those material which can be processed into particles using spray drying, atomization, grinding or other standard methods, or those*

> *materials which can be formed into emulsions, microparticles, liposomes or other small particles, and which remain stable chemically and retain biological activity in a polymeric matrix, are preferred. Bioactive agents also include compounds having principally a structural role, for example, hydroxyapatite crystals in a matrix for bone regeneration. The particles may have a size of greater than or less than the particle size of the polymer particles used to make the repair device.*
>
> *Examples of such bioactive materials generally include proteins and peptides, nucleic acids, polysaccharides, lipids, and non protein organic and but not limited to, anti-inflammatories, inorganic compounds, referred to herein as "bioactive agents" unless specifically stated otherwise. These material have biological effects including, antimicrobials, anti-cancer, antivirals, hormones, antioxidants, channel blockers, and vaccines. It is also possible to incorporate materials not exterting a biological effect, such as air, radiopaque materials, such as barium, or other imaging agents.*
>
> *The bioactive agents can be incorporated in the devices by adding both the bioactive agent and the biodegradable monomer to the precursor prior to polymerizing the precursor in situ,"*

see col. 25, line 26 through col. 26, line 18. Therefore at time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al., as taught by Bose et al. to provide the polymer with a bioactive agent in order to obtain various desirable results as noted above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. A.R.
January 19, 2006

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER